

DEC | 2 1997

Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

Gary A. Adler
Fuginon, Inc.
c/o Marks and Murase
399 Park Avenue
New York, NY 10022-4689

Re: K971528

Endoscopically Deliverable Ultrasound Point Probe System (SP-701) Dated: September 19, 1997

Received: September 19, 1997

Regulatory Class: II

21 CFR 892.1560/Procode: 90 IYO 21 CFR 892.1570/Procode: 90 ITX 21 CFR 892.1500/Procode: 78 KOG

#### Dear Mr. Adler:

We have reviewed your section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug and Cosmetic Act. You may, therefore, market the device, subject to the general controls provisions Act (Act). The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Encoscopically Deliverable Ultrasound Point Probe System (SP-701), as described in your premarket notification:

#### Transducer Model Number

PL-1726-20	PL-1726-15	PL-1726-12	PL-1926-20
PL-1926-15	PL-1926-12	PL-2226-20	PL-2226-15
PL-2226-12			

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Please be advised that the determination above is based on the fact that no medical devices have been demonstrated to be safe and effective for in vitro fertilization or percutaneous umbilical blood sampling, nor have any devices been marketed for these uses in interstate commerce prior to May 28, 1976, or reclassified into class I (General Controls) or class II (Special Controls). FDA considers devices specifically intended for in vitro fertilization and percutaneous umbilical blood sampling to be investigational, and subject to the provision of the investigational device exemptions (IDE) regulations, 21 CFR, Part 812. Therefore, your product labeling must be consistent with FDA's position on this use.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration Center for Devices and Radiological Health Document Mail Center (HFZ-401) 9200 Corporate Boulevard Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Paul Gammell, Ph.D., at (301) 594-1212.

Sincerely yours,

Lillian Yin, Ph.D.

Director, Division of Reproductive,

Abdominal, Ear, Nose and Throat,

and Radiological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure(s)

Ultrasound Device Indications Statement Page of 3

K971528

510(k) Number (if known): K971528

Device Name: Endoscopically Deliverable Ultrasound Point Probe System Device Name: SP-/01

Fill our one form for each ultrasound system or transducer.

Indications For Use: Diagnostic ultrasound imaging or Doppler analysis

(Specify) of the human body as follows:

				·	He	do of Opera	Fior	المراجعي المراجعين		
Climical Application	A	В	М	PWb	CMD	Color Doppler	Power (Aspirude) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Tetal										
Abdominal				<u> </u>						
latre-operative (Specify)										
Intra-operative Neurological										
Pediatric									ļ	ļ
Small Organ (Specify)										
Noonatal Cophalic										
Adult Cophalic		İ								
Cardina Adult										
Cardiac Podiatric					i					
Trans-esophageal										
Trans-receal										
Trans-vaginal										
Ingra-luminal		X								
Trans-urethral										
Peripheral					٠					
Laparoseopic ther Indicatio					_					

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Other	Indications	of	Modes:_				
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Presc	ription Use	(Per	21 CFR	801.109)	and	Radiological Dey	ices 77/528
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Ultrasound Device Indications Statement	Pageof	
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K971528 510(k) Number (if known): K97.
Device Name: SP-701 PL-1726-20 20 MHz Transducer

Fill our one form for each ultrasound system or transducer.

Indications For Use: Diagnostic ultrasound imaging or Doppler analysis (Specify) of the human body as follows:

Hode of Operation Combined Öther Color CND Color Power PWD Clinical (Ampieudo) (Specify) (Specify) Velocity Doppler Application Itaging Doppler Ophrhaimic Yetal Abdominal Intra-operative (Tirengs) Intra-operative Neurological Pediatric Small Organ (Specify) Magnatal Cophalic Adult Caphalic Cardias Adult Cardiac Podiatric Trans-coopbagen! Trans-ructal Trans-vegical Intra-luminal Trans-urethral Peripheral -Other Indications or Hodes:

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Division of Reproductive, Abdominal, ENT,

and Radiological Devices

510(k) Number <u>K97/5</u>28

Ultrasound Device Indications Statement Page\_\_\_

K971528 510(k) Number (if known): \_\_\_ B Device Name: SP-701 PL1726-15 15 MHz Transducer

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Fill our one form for each ultrasound system or transducer.

Indications For Use: Diagnostic ultrasound imaging or Doppler analysis

(Specify) of the human body as follows:

Clinical Application	A	3	н	2110	CWD	Deppler Colox	Power (Ampicude) Boppler	Color Velocity Imaging	Combined (Specify)	(Specity)
Ophshalmic										<del>                                     </del>
Fotal										<del> </del>
Abdominal										<del></del>
Inura-operative ( <b>Specify</b> )										
Intra-operative Nourological										<u> </u>
Padiatric										1
Small Organ (Specify)										
Neematal Cophalic										
Adult Cophalic										<del> </del>
Cardine Adult	<u> </u>									
Cardias Podiasric										
Trans-evophagen)										<del></del>
Trans-rectal							<u></u>	<u> </u>	<u> </u>	
Trans-vegical										
Intra-luminal		X								
Trans-urashçal								<u> </u>	<u> </u>	
Peripheral Persol	_						·	<u> </u>	<u></u>	
Lapasoscopic						]			1	

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Prescription Use (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal, ENT,

and Radiological Devices

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Ultrasound Device Indications Statement Page 4 of 13

K971528 510(k) Number (if known): Device Name: SP-701 PL-1726-12 12 MHZ Transducer

Fill out one form for each ultrasound system or transducer.

Indications For Use: Diagnostic ultrasound imaging or Doppler analysis

(Specify) of the human body as follows:

Hode of Operation										
Clinical Application	A	В	н	PWD	CAD	Color Doppler	Power (Ampitude) Doppies	Color Velocity Imaging	Combined (Specify)	Ochur (Specify)
Ophebalmic									<u> </u>	
Fetal										
Abdonissi									ļ	
Intra-operative (Specify)					]					
Intra-operacive Neuvological										
Padjetric										
Small Organ (Spanity)							·			
Necestal Caphalic										
Adult Caphalic										
Cardiac Adult										
Cardiac Podiatric										
Trans-orophageal										
Trans-rectal										
Trans-vegical										
Intra-luminal		X								
Trans-urethral										
Peripheral Vocana										
Laparoscopie her Indicatio										

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Division of Reproductive, Abdominal, ENT,

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K971528 510(k) Number (if known): K971528
Device Name: SP-701 PL-1926-20 20 MHz Transducer

Fill out one form for each ultrasound system or transducer.

Indications For Use: Diagnostic ultrasound imaging or Doppler analysis

(Specify) of the human body as follows:

				<u>-</u>	) de	do of Open	12100			
Clinical Application	A	3	н	PUD	CNO	Color Doppler	Power (Ampitude) Bopplor	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthelmic									ļ	ļ
Potal										<u> </u>
Abdominul	<u> </u>									<u> </u>
Intra-operative (Specify)										
Intra-operacive										ļ <u>.</u>
Pediatric										
Small Organ (Specify)										
Nootatal Cophalic										
Adult Cophalic										<u> </u>
Cardine Adult										
Cardiac Podiacric										
Trans-esophageni										
Trans-rectal										
Trans-vaginal										
Intre-luminal		X								
Trans-urenbysl										
Peripheral Tessel										
Laparoscopic					[					

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Prescription Use (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal, ENT,

and Radiological Devices

510(k) Number\_

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510(k)	Number	(if known)	K971528	16 301-	Transducer
Device	Name:	SP-701	PL-1926-15	15 MMZ	Transducer

Fill our one form for each ultrasound system or transducer.

Indications For Use: Diagnostic ultrasound imaging or Doppler analysis

(Specify) of the human body as follows:

						do of Open				
Clinical Application	A	В	ĸ	PWD	CND	Color Deppler	Power (Ampitude) Dopplet	Color Velocity Inceing	Combined (Specify)	(Epocity)
Ophuhalmic										
Feral		<u> </u>						ļ		<del> </del>
Abdoninai										ļ
Inura-operacive (Specify)										
larra-operacios Neurological										ļ
Pediatric										<u> </u>
Small Organ (Specify)										
Noomatal Caphalic										
Adult Cophalic										
Cardine Adult									<u> </u>	
Cardiac Podiacric										
Trans-scophages1										
Trams-receal										
Trans-vegius!										
latro-luminal		X								<u> </u>
Trans-urechrol										
Posipheral Possel										
Laparoscopic										l

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Division of Reproductive, Abdominal, ENT,

and Radiological Devices

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### Ultrasound Device Indications Statement Page of 13

510(k) Number (if known): K971528

Device Name: SP-701 PL-1926-12 12 MHz Transducer

Fill out one form for each ultrasound system or transducer.

Indications For Use: Diagnostic ultrasound imaging or Doppler analysis

(Specify) of the human body as follows:

Node of Operation										
Clinical Applicacion	A	В	H	PWD	CVID	Color Doppler	Power (Ampitude) Doppler	Color Volocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Peral.		<u> </u>		Ĺ						
Abdominal										
Intra-operative (Specify)										
Intra-operative Neurological										
Pediatric		<u> </u>							ļ	
Small Organ (Spanity)	<u> </u>									
Necestal Cophalic										
Adult Caphalic										
Cardiac Adulx										
Cardiaa Pediatric										
Trans-esophages1							·			
Trans-rectal										
Trans-vaginal										
Intra-luminal		X								
Trans-uretheal										
Peripheral Vessel						·				
Laparoscopic										

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Prescription Use (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal, ENT,

and Radiological Devices

510(k) Number \_

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# Ultrasound Davice Indications Statement Page 8 of /3

K971528

510(k) Number if known): K971528
Device Name: SP-701 PL-2226-20 20 MHz Transducer

Fill our one form for each ultrasound system or transducer.

Indications For Use: Diagnostic ultrasound imaging or Doppler analysis

(Specify) of the human body as follows:

Hode of Operation										
Clinical Application	A	3	н	PWD	CHB	Color Doppler	Power (Ampirude) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic									<u> </u>	
Foral										
Abdominal										
Intra-operative (Specisy)										
Intra-operative Feurological										
Podiatric										
Small Organ (Specify)										
Mecastel Cephalic										
Adult Caphalic										
Cardine Adult										
Gerdiac Podistric										
Trans-eroptagenl										
Trans-rectal									<u></u>	
Trans-vegical										
Intra-luminal		X								<u> </u>
Trans-wrothesl										
Peripheral vessel										
Laparoscopia										

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Division of Reproductive, Abdominal, ENT, and Radiological Devices

# Ultrasound Device Indications Statement Page 9 of /3

510(k) Number (if known): K971528

Device Name: SP-701 PL-2226-15 15 MHz Transducer

Fill our one form for each ultrasound system or transducer.

Indications For Use: Diagnostic ultrasound imaging or Doppler analysis (Specify) of the human body as follows:

Mode of Operation

Clinical Application	A	B	H	PVD	CARD	Color Deppler	Power (Ampirude) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Potal					<u> </u>					ļ
Abdominal										
latta-operative (Specify)										
Latre-operative										
Pediatric										
Sumil Organ (Specify)										
Mecantal Cophalic										
Adult Cophalic										
Cardisc Adult										
Cartise Podiatrie										
Trans-scopinges!										
Trass-rectal										
Trans-vaginal										
Incre-luminal		X								
Trans-urethral							-			
Poripheral vessel									•	
Laparoscopia		I								

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Prescription Use (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal, ENT,

and Radiological Devices

510(k) Number <u>K97/5</u>

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### Ultrasound Device Indications Statement Page 10 of 13

K971528 510(k) Number (if known): Device Name: SP-701 PL-2226-12 12 MHz Transducer

Fill out one form for each ultrasound system or transducer.

Indications For Use: Diagnostic ultrasound imaging or Doppler analysis

(Specify) of the human body as follows:

Climical Application	^	В	н	PVD	വര	Color Doppler	Power (Ampitude) Poppler	Color Volocity Imaging	(Specify)	Other (Specify
Ophrhalmic									<u> </u>	
Potal										<u> </u>
Abdominal		<u></u> .	<u> </u>							
Intra-operative (Specify)										
Intra-operative Meusulogical										
Podiatric	1									
Small Organ (Specify)										
Necescal Caphalic										
Adult Cophalis										<u> </u>
Cardine Adult										
Cardiso Podistric										
Trans-sophageal										
Trass-rectal										
Trans-veginal										
Incra-luminal		X								
Trans-ure thral										
Peripheral Pessel										
Laparoscopic										

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Prescription Use (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal, ENT,

and Radiological Devices

510(k) Number\_

Ultrasound Device Indications Statement Page 11 of 13

510(k) Number (if known): K971528

Device Name: SP-701 PL-2220-20 20 MHz Transducer

Fill out one form for each ultrasound system or transducer.

Indications For Use: Diagnostic ultrasound imaging or Doppler analysis

(Specify) of the human body as follows:

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Clinical Application	٨	В	H	2110	CHRD	Color	Power (Ampitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	L.									
Fetal										
Abdominal										
Intra-operative (Specify)										
Intra-operative Neurological										
Pediatric										<u> </u>
Small Organ (Specify)										
Neonatal Caphalic										
Adult Cophalic										
Cardiac Adult										
Cardiae Podiatric										
Trans-esophageal										
Trans-rectal										
Trans-vaginal										
Intra-luminal	X									
Trans-urethral										
Peripheral vessel										
Laparoscopic ther Indication										

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Prescription Use (Per 21 CFR 801.109)



Ultrasound Device Indications Statement Page 12 of 13

510(k) Number (if known): <u>K971528</u>

Device Name: <u>SP-701 PL-2220-15 15 MHz Transducer</u>

Fill out one form for each ultrasound system or transducer.

Indications For Use: Diagnostic ultrasound imaging or Doppler analysis

(Specify) of the human body as follows:

Hode of Operation

				-		de of Oper				
Clinical Application	A	В	н	PVD	CWD	Color Doppler	Power (Ampitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic							 			
Fotal										
Abdominal										
Intra-operative (Specify)										
Intra-operative Neurological										
Pediatric										
Small Organ (Specify)										
Necental Cephalic										
Adult Cophalic										
Cardiac Adult										
Cardiae Pediatric										
Trans-esophageal										
Trans-rectal										
Trans-vaginal										
Intra-luminal	Х									
Trans-urethral										
Peripheral wessel										
Laparoscopic										

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# Ultrasound Device Indications Statement Page 13 of 13

510(k) Number (if known): K971528

Device Name: SP-701 PL-2220-12 12 MHz Transducer

Fill out one form for each ultrasound system or transducer.

Indications For Use: Diagnostic ultrasound imaging or Doppler analysis

(Specify) of the human body as follows:
Node of Operation

Clinical Application	٨	3	н	PWD	CWD	Color Doppler	Power (Ampitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify
Ophthalmic										
Fetal										
Abdominal							!			
Intra-operative (Specify)										
Intra-operative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cophalic										
Adult Caphalic										
Cardiac Adult										
Cardiac Pediatric										
Trans-exophageal										
Trans-rectal								,		
Trans-vaginal										
Intra-luminal	X									
Trans-urethral										
Peripheral Vessel										
Laparoscopie										

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